Templates Part II
Interim Progress Report - Budget Period Three
Workplan - Budget Period Four
Focus Area C: Laboratory Capacity—Biologic Agents

Budget Period Three Progress Report

Using the Interim Progress Report template below, provide a brief status report that describes progress made toward achievement of each of the *critical capacities* and *critical benchmarks* outlined in the continuation guidance issued by CDC in February 2002. Applicants should describe their agency's overall success in achieving each critical capacity. The progress report narratives should not exceed 1 page, single-spaced, for each critical capacity. Applicants are welcome to use bullet-point format in their answers, so long as the information is clearly conveyed in the response.

CRITICAL CAPACITY: To develop and implement a jurisdiction-wide program to provide rapid and effective laboratory services in support of the response to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies.

Provide an update on progress during Project Year III toward achieving this critical capacity:

The Massachusetts State Laboratory Institute (SLI) operates a statewide program that provides rapid and effective laboratory services to support preparedness and response to bioterrorism, other infectious diseases and other public health emergencies and threats. This capacity is guided by a strategic and implementation plan. Ininitiatives to strengthen this capacity are on-going; activities during the past year are described here.

- Completed preparation of a timeline for the development of a plan to improve working relationships and communication between sentinel laboratories and confirmatory LRN laboratories (Critical Benchmark 10)
- Convene meetings of a Statewide Laboratory Advisory Workgroup consisting of hospital and university laboratorians
- Provide and continually update an "Agents of Bioterrorism: Sentinel Laboratory Training" lecture and wet lab course attended by 66 of 73 sentinel hospital laboratories with a total of 121 microbiologists trained, as well as microbiologists from Tufts University Veterinary School , IDEXX Laboratories (commercial animal health lab), Massachusetts Water Resources Authority, Environmental Protection Agency, Department of Environmental Protection, National Guard 1st Civil Support Team (CST), State Hazardous Materials (HazMat) teams, State Police Crime Laboratory and the U.S. Army Soldier and Biological Chemical Command Unit
- Provide and continually update a "Packaging and Shipping Diagnostic Specimens and Infectious Substances" course attended by 38 of 73 sentinel hospital laboratories with a total of 108 microbiologists trained
- Designed and provided a "Critical Bioterrorism Agents Reference Chart" poster depicting morphological and phenotypic characteristics of Category A threat agents to all sentinel laboratories and Hospital Chiefs of Infectious Disease
- Developed a "Proficiency Exercise for Sentinel Laboratories: Agents of Bioterrorism Level-A Laboratory Training" interactive web based learning tool that will be offered to all sentinel laboratories
- Provide and continually update an on-line "Manual of Tests and Services" to provide laboratories with current information on test profiles, test kits, proper samples and shipping requirements
- Initiated a pilot test of a courier system for transport of clinical samples from hospitals
- Provide a pustular rash illness specimen kit with LRN sampling handling protocols to the MDPH smallpox

response team members

- Established a point of contact within the CST, state and local HazMat teams, State Police, State Fire Academy, Boston Fire Department, and Boston Police Department
- Developed a CD ROM presentation entitled "Recognition of Rudimentary and Conventional Laboratory Equipment" for the State Police
- Collaborate with the Department of Fire Services State Fire Academy to distribute to local fire departments an electronic learning tool consisting of suggested protocols for determining risk, safely packaging specimens and submitting specimens to the SLI
- Provide environmental sample collection kits and distribute these kits to state and local HazMat teams and fire and police departments on an as needed basis
- Attend and present at various first responder meetings and courses
- Participate in all workgroups of the Statewide Bioterrorism Preparedness and Response Program Advisory Committee
- Provide 24/7 response for confirmatory testing of all Category A agents with LRN protocols for conventional and rapid methods including HSV and conventional cell culture for enteroviruses
- Maintain supply and staffing ability to test a surge of 500 specimens with contracts in place to order additional supplies if needed
- Hired 11 BT staff, five management support and six technical
- Attend presentations by State Police Crime Lab and the FBI to better understand the handling of forensic evidence and chain of custody
- Developed protocols for prioritizing testing for environmental specimens according to presence of a verbal or written threat, likelihood of target, presence of visible powder and number of exposed victims
- Esatblished access to an electron microscope for pustular rash testing at the Harvard School of Public Health
- Improved LIS for support of reporting clinical and environmental test results in real time by telephone to the appropriate persons with a hard copy of the report sent by mail to submitting hospitals, first responders and local public health departments
- Completed the conceptual design of the web-based Electronic Laboratory Reporting application

Critical Benchmark #10: Has your state developed a plan to improve working relationships and communication between Level A (clinical) laboratories and Level B/C Laboratory Response Network labs to ensure Level A core capabilities (perform rule-out testing on critical BT agents, safely package and handle specimens, refer to higher level (B/C) labs for further testing) ?

☒ YES ☐ NO

CRITICAL CAPACITY: As a member of the Laboratory Response Network (LRN), to ensure adequate and secure laboratory facilities, reagents, and equipment to rapidly detect and correctly identify biological agents likely to be used in a bioterrorist incident.

Provide an update on progress during Project Year III toward achieving this critical capacity:

The SLI ensures rapid and correct detection and identification of biological agents through adequate and secure staffing, facilities, reagents and equipment.

Staffing

- trained five bioterrorism (BT) staff in conventional microbiological and virologic procedures, four in TRF

procedures and eight in PCR procedures

- trained primary BT staff on all LRN validated assays and gave a proficiency test to demonstrate competency twice a year
- trained and certified 23 SLI staff to properly package and ship bioterrorism-related specimens
- provided a refresher course on the use of full-face respirators to BT personnel
- provided biosafety cabinet training to 61 SLI staff (Eagleson Institute)
- cross-trained staff from other departments to process specimens and perform data entry and management for surge capacity
- vaccinated 14 staff for anthrax and 3 staff for smallpox

Facilities

- selected and established a contract for design for renovation of BSL-3 laboratory areas (SMMA Hoskins Scott architectural, engineering and planning firm)
- designated a Responsible Official and three alternates that ensure regular review and compliance with select agent regulations
- applied for a certificate of registration and have received a temporary registration number for select agents
- installed controlled access systems (electronically recorded proximity readers and fingerprint scanners on all entries and exits) on all laboratories handling select agents
- installed emergency release buttons on each of the proximity card restricted laboratories as well as the inner rooms of labs with interlocking doors
- conducting a risk assessment of SLI with members of the Massachusetts State Police Task Force

Reagents

- ensures quality control of all BT reagents and media through monthly review of media/reagent logs, BT test logs, temperature charts, problem logs, pipette calibration records and employee competency records
- stores all known or suspect select agents under BSL-3 laboratory conditions with locking devices on refrigerators, freezers and incubators containing these agents

Equipment

- ensures availability of equipment including one ABI 5700, two ABI 7000s, two Smart Cyclers, two iCyclers, one Light Cycler, one MJR Tetrad, two Beckman Coulter DNA sequencers and one Victor time-resolved fluorescence instrument
- purchased and are developing protocols for an area radiation monitor, radiation survey meters and an ion mobility detector for screening incoming specimens for radiation, explosives and chemicals

Budget Year Four Workplan

For each Recipient Activity applicants should complete the work plan templates attached below. Applicants are welcome to use bullet-point format in their answers, so long as the information is clearly conveyed in the response. All responses should be brief and concise. **Please note that full use of the CDC templates will meet all of the requirements for submission of a progress report and work plan**. Although no additional information is required, grantees may elect to submit other essential supporting documents via the web portal by uploading them as additional electronic files.

CRITICAL CAPACITY #8: To develop and implement a jurisdiction-wide program to provide rapid and effective laboratory services in support of the response to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies.

RECIPIENT ACTIVITIES:

1. Develop and maintain the capability of Level A (sentinel) laboratories to (a) perform rule-out testing on critical BT agents, (b) safely package and handle specimens, and (c) refer to LRN Level B/C (reference/confirmatory) laboratories for further testing. **(LINK WITH FOCUS AREAS D AND G AND HRSA PRIORITY AREA #4)**

Strategies: What overarching approach(es) will be used to undertake this activity?

The overarching approach that continues to be used to undertake this activity includes the active recruitment of all sentinel laboratories in Massachusetts to participate in the "Agents of Bioterrorism: Sentinel Laboratory Training" and the "Packaging and Shipping Diagnostic Specimens and Infectious Substances" courses offered by the Massachusetts State Laboratory Institute (SLI) free of charge. Further enhancements to this approach will include the addition of a Chemical Agent Response Course (as outlined in Focus Area D) and the implementation of the interactive web-based "Proficiency Exercise for Sentinel Laboratories: Agents of Bioterrorism Level A Laboratory Training", which will be made available to all sentinel laboratories. In addition, SLI will strengthen sentinel laboratory capacity and surge capacity through cross-cutting initiatives with the HRSA-funded clinical laboratory activities.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

- The SLI will schedule monthly meetings of the Statewide Laboratory Advisory Workgroup to direct strategic planning and coordination with the sentinel hospital laboratories and develop surge capacity.
- The SLI continues to update the online "Manual of Tests and Services" to provide sentinel laboratories with current information on test profiles and test kits, critical contact information, and proper samples and shipping requirements (http://www.state.ma.us/dph/bls/manual/blsmts.htm).
- The "Agents of Bioterrorism: Sentinel Laboratory Training" course curricula currently provides a lecture and wet lab overview of the sentinel laboratories' role in the presumptive identification of primary agents of bioterrorism (BT) including: *Bacillus anthracis, Yersinia pestis, Francisella tularensis, Brucella sp., Variola major* (lecture only), *Clostridium botulinum*, and Ricin Toxin. This course is offered twice a month with 8 students per session. At this time, 66 of 73 Massachusetts sentinel hospital laboratories have had at least one microbiologist attend the training with a total of 121 microbiologists trained. The SLI will add course material on additional BT agents as the Laboratory Response Network (LRN) finalizes protocols.
- The SLI will continue to train additional microbiologists from each sentinel laboratory in addition to ensuring that at least one microbiologist from each laboratory is trained.

- The SLI will develop an "Agents of Bioterrorism: Sentinel Laboratory Training" refresher course for previously trained microbiologists, which will include materials on those BT organisms recently added to the original course curriculum.
- The SLI has developed a "Critical Bioterrorism Agents Reference Chart" poster that depicts morphological and phenotypic characteristics of BT organisms. This poster has been distributed to each sentinel laboratory Microbiology Supervisor and each hospital Chief of Infectious Disease in the State. SLI will develop a similar poster as protocols for additional BT agents are released by the LRN.
- The "Packaging and Shipping Diagnostic Specimens and Infectious Substances" course curricula provides a lecture and hands on overview of IATA, DOT, CDC, USPS and specific carrier regulations applicable to packaging and shipping both diagnostic and infectious agents including the terminology, packaging, marking, labeling and documentation required by these regulations. Participation in classroom exercises and successful completion of a written examination are requirements for certification. Curricula are updated on a yearly basis according to revised regulations. This course is offered monthly with 20 students per session. At this time, 36 of 73 Massachusetts sentinel laboratories have had at least one microbiologist attend with a total of 108 microbiologists trained. During budget period four, SLI will continue to train additional microbiologists from each sentinel laboratory to ensure that at least one microbiologist from each laboratory is trained.
- SLI has contracted with Acadient, Inc., a premier online learning company, to develop an interactive web-based learning tool, "Proficiency Exercise for Sentinel Laboratories: Agents of Bioterrorism Level A Laboratory Training", which will be made available to all sentinel laboratories. This learning tool is made up of 10 case studies, eight of which require the participant to rule in or out a BT agent, and two of which require the participant to make decisions on packaging and shipping specimens. This electronic course will be offered to those laboratories that have participanted in the "Agents of Bioterrorism: Sentinel Laboratory Training" as an aid to training additional microbiologists.
- The SLI will hire an LRN Medical Technologist to visit individual sentinel laboratories to assist in determination of testing capacity, development/improvement of testing competencies and coordination of the transportation protocols to be used during biological or chemical agent events. This employee will work directly with the HRSA Coordinator to carry out activities outlined in the HRSA Priority Area 4-1 such as development of a laboratory resource survey and letters of agreement allowing for direct grants to hospital laboratories and identification of approximately three surge laboratories.
- The SLI will develop a Chemical Agent Response Course and a Sample Handling and Transport course for sentinel laboratories as outlined in Focus Area D Critical Capacity #10.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/ Completion Date*	*Responsible Party*
Reconvene Statewide Laboratory Advisory Workgroup	09/03	Ralph Timperi, Director, SLI
Coordinate and facilitate training courses for sentinel laboratories	On going	Garry Greer, Laboratory Training and Distance Learning Coordinator Sam Brelsfoard, Administrative Assistant
Update and teach curricula of "Agents of Bioterrorism: Sentinel Laboratory Training" course	On going	Sandra Smole, BioThreat and Advanced Technology Laboratory Director Cheryl Gauthier, BioThreat and Advanced Technology Laboratory Supervisor
Update and teach curricula of Packaging and Shipping course	On going	Phyllis Madigan, Laboratory Client Services
Complete curricula of "Proficiency Exercise for Sentinel Laboratories: Agents of Bioterrorism Level A Laboratory Training" electronic course	On going- 07/03	Cheryl Gauthier Phyllis Madigan
Beta test and evaluate Proficiency Exercise electronic course	07/03-08/03	Garry Greer Ralph Timperi
Implement Proficiency Exercise electronic course	09/03- On going	Garry Greer Cheryl Gauthier
Develop and teach curricula of "Agents of Bioterrorism: Sentinel Laboratory Training" refresher course	08/03-02/03	Sandra Smole Cheryl Gauthier
Hire LRN Medical Technologist for sentinel laboratory site visits	09/03-11/03	BT Interview Committee (Chair, Barbara Werner, Deputy Director, SLI)
Develop second "Critical Bioterrorism Agents Reference Chart" poster	01/04-04/04	Garry Greer Cheryl Gauthier
Develop and conduct sentinel lab survey	12/03-02/04	Mariah Grazioplene, Laboratory Emergency Preparedness Coordinator
Conduct sentinel lab site visits	02/04- On going	Peter Belanger

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

The SLI will track progress toward completing each task using Microsoft Project software. Site visits and the "Proficiency Exercise for Sentinel Laboratories: Agents of Bioterrorism Level A Laboratory Training" electronic course will be used to evaluate competency of individual sentinel laboratories, and will determine which laboratories need to attend refresher courses.

2. **CRITICAL BENCHMARK #12:** Complete and implement an integrated response plan that directs how public health, hospital-based, food testing, veterinary, and environmental testing laboratories will respond to a bioterrorism incident, to include: (a) roles and responsibilities; (b) inter- and intrajurisdictional surge capacity; (c) how the plan integrates with other department-wide emergency response efforts; (d) protocols for safe transport of specimens by air and ground; and (e) how lab results will be reported and shared with local public health and law enforcement agencies, ideally through electronic means. **(LINK WITH FOCUS AREAS A, B, D, E AND F, and CROSS CUTTING ACTIVITY *LABORATORY CONNECTIVITY*, Attachment X)**

Strategies: What overarching approach(es) will be used to undertake this activity?

The SLI integrated response plan currently includes provisions for clinical hospital-based and environmental (e.g. white powder) testing. In addition, initiatives are in process to strengthen links with veterinary laboratories and supplement existing food testing capabilities at SLI. Specifically, for veterinary testing, SLI will build on existing relationships with the Bureau of Animal Health, USDA, Tufts University Veterinary School, and Zoo New England in dealing with BT agents, rabies, eastern equine encephalitis virus and West Nile virus surveillance and testing.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

Roles and Responsibilities

- The SLI serves as the reference laboratory for clinical and environmental samples for the state in collaboration with the Bureau of Communicable Disease (CD), local hospitals, and first responders.
- The SLI currently works with the CD Bureau to investigate agents associated with food-borne illness and will initiate efforts to develop capability to test for BT agents, and collaborate with the Mass. Department of Environmental Protection (DEP) laboratory to test BT agents in water samples.
- Microbiologists from Tufts University Veterinary School and IDEXX Laboratories, a commercial animal health diagnostic laboratory in Massachusetts, have attended the "Agents of Bioterrorism: Sentinel Laboratory Training" course at SLI. This laboratory serves many private veterinarian clinics in the state as well as the Boston Aquarium and local zoos. SLI will collaborate with IDEXX to develop strategies for specimen referral and reporting.
- Representatives from environmental laboratories including the Massachusetts Water Resource Authority, Mass. Department of Environmetal Protection and U.S. Environmental Protection Agency have attended the "Agents of Bioterrorism: Sentinel Laboratory Training" course.
- The SLI plans to collaborate with the Bureau of Animal Health and the Wildlife Clinic at Tufts University Veterinary School on a sentinel surveillance initiative for the screening of unexplained deaths in wildlife, livestock and domestic animals. A plan will be developed detailing sample collection, shipping, receiving, testing and reporting of results.
- SLI will meet with representatives of Tufts University Veterinary School and University of Massachusetts South Dartmouth to discuss development of in vitro assays for *Clostridium botulinum* toxin and a collaboration to validate these assays through an AOAC process including comparison to current LRN protocols and to begin drafting plans for a surge capacity laboratory to assist SLI in testing for *Clostridium botulinum* toxin.

Inter- and intrajurisdictional surge capacity

- SLI will work through the Statewide Laboratory Advisory Workgroup to complete a plan for assessing the need for surge capacity for clinical, food, veterinary and environmental testing with input from the New England Environmental and Public Health Laboratory Directors committee.
- Under HRSA funding, three sentinel laboratories will be identified as surge capacity sites for clinical testing.
- SLI serves as a regional lab to test samples from Maine, Vermont, New Hampshire and Rhode Island.
- As a resource for the National Laboratory Training Network, SLI has offered a two-day train-the-trainer course in

"Packaging and Shipping Diagnostic Specimens and Infectious Substances" to 15 individuals in the Northeast Region of the United States.

Integration with other department-wide emergency response efforts

- SLI will update our laboratory response plan to include food, veterinary and chemical testing.
- The laboratory response plan is integrated department-wide through a Bioterrorism Workgroup that meets biweekly to assure effective communication between MDPH bureaus and all grant Focus Areas.
- MDPH has embedded employees at the Massachusetts Emergency Management Agency (MEMA) and the State Department of Fire Services Regional HazMat Response Units to assure coordination with the state emergency response plans.
- SLI staff participate in the Statewide Bioterrorism Preparedness and Response Program Advisory Committee and Workgroups that meet regularly to plan, implement and coordinate all aspects and Focus Areas of the CDC and HRSA Bioterrorism Grants.
- SLI and the CD Bureau are exploring a collaboration with veterinarians on Martha's Vineyard to conduct a serosurveillance study of *Francisella tularensis* in the domestic animal population.

Protocols for safe transport of specimens by air and ground

- SLI offers a packaging and shipping course as described in Critical Capacity 8, Recipient Activity 1.
- SLI will build upon existing pilot courier programs to expand coverage throughout the state for transport of specimens.

Reporting of lab results to local public health and law enforcement

- SLI staff currently report laboratory results of environmental specimens to appropriate local first responders, FBI, and United States Postal Inspectors by telephone and US mail. The MDPH CD Bureau reports laboratory results to appropriate local public health by telephone and US mail.
- SLI will develop a web-based, secure electronic laboratory reporting system for sending results to hospitals, local health departments and first responders to supplement and enhance current reporting. This task will be integrated with Focus Area E and the HRSA Cooperative agreement.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/ Completion Date*	*Responsible Party*
Assess feasibility of tularemia veterinary study	07/03	Ralph Timperi (SLI Lab Director)
Develop protocols of tularemia study	08/03-10/03	Frederic Cantor (CD Bureau) Cheryl Gauthier (BioThreat and Advanced Technology Lab Supervisor)
Update integrated response plan	On going	Mariah Grazioplene (Lab Preparedness Program Coordinator)
Expand courier program	12/03- On going	Mariah Grazioplene
Collaborate with IDEXX Laboratories	12/03- On going	Cheryl Gauthier
Unexplained animal deaths surveillance study with Tufts University Veterinary School		
Meet with representatives from Bureau of	07/03	Cheryl Gauthier

	Meet with representatives from Bureau of Animal Health and Tufts Veterinary School	07/03	Cheryl Gauthier John Fontana (PFGE and Surveillance Director)
	Develop protocols	08/03-12/03	Cheryl Gauthier John Fontana David Sherman (Bureau of Animal Health) Tufts Vet School
	Begin sentinel testing for BT select agents	01/04- On going	Sandra Smole
Meet with representatives from Tufts and UMASS Dartmouth		08/03	Ralph Timperi
Assess need for surge capacity		01/04-04/04	Ralph Timperi; Statewide Laboratory Advisory Workgroup
Identify sentinel surge capacity labs		05/04-08/04	Ralph Timperi
Develop electronic reporting system		07/03 – On going	Siu Leung Cheung (EDP Systems Analyst) TBD (EDP Systems Analyst)

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

Progress will be monitored through the biweekly department meetings of the Bioterrorism Workgroup. Responsibility for specific activities are assigned to senior staff, who report on progress at weekly Bioterrorism Laboratory Committee meetings and other frequent interations with Laboratory Directors who support activities, identify problems and provide supplemental assistance as needed to assure success. Progress on workplan activities is presented to the Statewide Bioterrorism Advisory Committee Quarterly Meetings.

3. In accord with Critical Benchmark #12, address the identified needs for testing food specimens for critical BT pathogens. This may be done by contracting for services with laboratories that possess the requisite capabilities, by sponsoring such capability development within collaborating organizations (such as food regulatory laboratories), and/or by developing the requisite capabilities directly within public health department laboratories. Technical assistance with respect to selection of analytic methods is available through FDA, in consultation with CDC (see Appendix 1 for FDA contact information).

Strategies: What overarching approach(es) will be used to undertake this activity?

The SLI will implement an internal program to ensure capacity to provide food testing for critical BT pathogens and subsequently add surge capacity partners. The BioThreat Advanced Technology (BAT) Laboratory Director will coordinate the following SLI laboratories: Food Testing; Milk Testing; and the PFGE and Antimicrobial Resistance Surveillance, a CDC PulseNet Regional Laboratory, to enhance cross-training and instrument capacity for this program.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

- SLI will hire a Food Microbiologist who will implement the interim FDA protocols provided on the LRN and will train additional staff.
- Funds are requested for laboratory renovations and equipment to update and exp and the food testing laboratory.
- New FDA approved protocols for food matrices are undergoing evaluation on the real time PCR BAX system at SLI.
- SLI collaborates with the U.S. Army Soldier and Biological Chemical Command food laboratory in Massachusetts and will investigate their interest and ability to provide sentinel testing and/or surge capacity for food testing. Members from this institution have attended Level A training courses.
- SLI will identify additional available laboratory partners in the state to handle sentinel food testing and/or surge capacity reference testing.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/ Completion Date*	*Responsible Party*
Cross-train personnel on LRN FDA Interim Food Testing Protocols for BT Agents	Ongoing- 12/03	Bob Goldbaum (Food Testing Laboratory Supervisor) John Fontana (PFGE and Surveillance Director) Sandra Smole (BioThreat and Advanced Technology Laboratory Director)
Renovate food laboratory	03/04-07/04	John Fontana
Hire Food Microbiologist	09/03-11/03	John Fontana; Bob Goldbaum
Identify laboratory partners for sentinel and reference food testing	10/03-03/04	Bob Goldbaum; Sandra Smole

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

The SLI will track progress of each task using Microsoft Project software. Weekly BT Laboratory Committee meetings will be used to discuss cross-training progress and interlaboratory collaboration.

4. Establish and maintain operational relationships with local members of HazMat teams, first responders, local law enforcement and FBI to provide laboratory support for their response to bioterrorism, including environmental testing for exposure assessment and chain-of-custody procedures. Examples of enhanced these relationships include designated points of contact, cross-training in each discipline, and/or joint sponsorship of conferences. **(LINK WITH FOCUS AREA D)**

Strategies: What overarching approach(es) will be used to undertake this activity?

The SLI currently maintains relationships with the first responder community and will continue and enhance these relationships by attending, presenting and facilitating conferences and meetings. The SLI will work with the first responder community to develop joint protocols for determination of environmental contamination, site security and

forensic environmental sampling of criminal incidents.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

Designated Points of Contact

- The SLI has designated Mariah Grazioplene, the Laboratory Emergency Preparedness Program Coordinator, as the point of contact for the first responder community.
- The SLI has established a point of contact within the National Guard 1st Civil Support Team (CST), State and local HazMat teams, State Police, State Fire Academy, Boston Fire Department, and Boston Police Department. In addition, MDPH has embedded employees at the Massachusetts Emergency Management Agency (MEMA) and the state Department of Fire Services Regional HazMat Response Units. The SLI will maintain these relationships and will develop relationships with the State Police Academy, Massachusetts Police Chiefs Association, and the Fire Chiefs' Association of Massachusetts.

Cross-training in Each Discipline

- Members of the CST, State HazMat, and State Police Crime Lab have attended the SLI's "Agents of Bioterrorism: Sentinel Laboratory Training" course. The SLI will continue to offer this course to additional members of these agencies.
- SLI has developed and made available to the State Police a CD ROM presentation entitled "Recognition of Rudimentary and Conventional Laboratory Equipment".
- The SLI is currently collaborating with the Department of Fire Services State Fire Academy to distribute an electronic learning tool for local fire departments. This tool consists of suggested protocols for determining risk, safely packaging specimens and submitting specimens to the SLI in responding to suspected environmental BT incidents. This tool will also be made available to local police departments.
- The SLI has assembled 5000 environmental sample collection kits and currently distributes these kits to HazMat teams, local fire and police departments on an as needed basis.
- Members of these agencies will also be invited to attend the "Introduction to Chemical Terrorism Agents" once developed by the Environmental Chemistry staff as outlined in Focus Area D, Critical Capacity 10.
- To allow for better understanding of their capabilities, the CST and State HazMat have presented their various technologies and instrumentation to SLI. The SLI will continue to invite first responder agencies to present as SLI gains new staff and as first responders gain new technologies.
- To allow for better understanding of handling forensic evidence and chain of custody, SLI staff have toured the State Police Crime Lab, and the FBI have given presentations to SLI staff. As SLI trains additional staff and adds a chemical testing component, these relationships will continue.

Meetings and Conferences

- SLI staff have and will continue to attend and/or present at various first responder meetings and courses such as: "Dugway Proving Ground: Detection Sampling and Analysis of Toxic Weapons Grade Biological and Chemical Agents", Anti Terrorism Task Force Trainings and meetings, "Bioterrorism Preparedness: A Conference for Senior Practitioners and Professionals" (Kennedy School of Government), "Bioterrorism: The Traditional Incident Command System for the Non-Traditional Responder" (Monroe County Health Department), "Annual Massachusetts Association of HazMat Technicians Conference".

Laboratory Support

- The SLI continues to work with the first responder community to provide testing of environmental samples determined to pose a risk.
- The SLI will enhance support by providing 24/7 consultation by laboratory staff to assist first responders in assessing risk and necessity of testing.
- The SLI will enhance support to first responders by contracting with a courier service to transport environmental specimens. In a post event scenario, SLI will arrange for DPH Food and Drug Inspectors to provide transport of specimens.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/ Completion Date*	*Responsible Party*
Establish points of contact with State Police Academy, Massachusetts Police Chiefs Association, and the Fire Chiefs' Association of Massachusetts	08/03- On going	Mariah Grazioplene (Laboratory Preparedness Program Coordinator) TBD (Asst. Preparedness Coordinator)
Establish and maintain 24/7 consultation	08/03- On going	Mariah Grazioplene
Provide 24/7 consultation	08/03- On going	SLI BT/CT staff
Distribution of electronic learning tool for first responders	10/03- On going	Phyllis Madigan (Director of Client Services) Mariah Grazioplene
Contract with courier service for environmental transport	12/03- On going	Phyllis Madigan

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

Project timelines will be tracked using Microsoft Project software. The SLI will ask for feedback from first responders on 24/7 consultation and courier services.

5. Enhance relationships with hospital-based laboratory practitioners, university laboratories, and infectious disease physicians through participation in infectious disease rounds and conferences. **(LINK WITH FOCUS AREA D)**

Strategies: What overarching approach(es) will be used to undertake this activity?

The enhancement of relationships with clinical and university laboratorians will occur through more frequent meetings of the Statewide Laboratory Advisory Workgroup, and the SLI will continue to enhance relationships with infectious disease (ID) physicians through participation in various professional medical organizations.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

- SLI continues to distribute updated "Manual of Tests and Services" to all hospital clinical laboratories as well as all Chiefs of Infectious Disease Physicians in Massachusetts.
- SLI Laboratory Director will chair the Statewide Laboratory Advisory Workgroup to identify needs of and enhance relationships with laboratory practitioners.
- SLI is currently working with the Harvard School of Public Health to set up an agreement for use of an electron microscope on an as needed basis (see Critical Capacity 9, Recipient Activity 8). The SLI will contact additional university laboratories in the state to explore surge capacity options.
- In conjunction with the Northeast Office of the National Laboratory Training Network (NLTN), the SLI continues to sponsor various laboratory training courses for in-state and out-of-state clinical, public health and university laboratorians.
- SLI will update protocols and procedures for ID physicians on the Massachusetts ID Society Website and

distribute these to hospitals to describe selection, collection and shipment of appropriate specimens for diagnosis of BT agents.

- The State Epidemiologist and the Deputy Director of SLI will continue to meet frequently with infectious disease practitioners at the Massachusetts ID Society and the Massachusetts Medical Society meetings and coordinate presentations of information on BT agents and diseases, including testing and diagnosis.
- State Laboratory Director and State Epidemiologist hold regular monthly conference calls with hospital infectious disease and emergency room practitioners through their consortia and professional organizations, e.g., Cambridge Health Alliance.
- Key staff routinely attend and present at the Northeast Branch of the American Society of Microbiology meetings.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/ Completion Date*	*Responsible Party*
Statewide Laboratory Advisory Workgroup	On going	Ralph Timperi (SLI Laboratory Director) Mariah Grazioplene (Laboratory Preparedness Coordinator)
Identification of additional testing capacity at university laboratories	On going	Ralph Timperi; SLI staff; Barbara Werner (SLI Deputy Director)
Interact with clinical practitioners	On going	Ralph Timperi; Barbara Werner; SLI staff

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

Progress will be realized when the SLI has routinely met (quarterly) with the Statewide Laboratory Advisory Workgroup and has communicated with university laboratories in the state regarding specific technologies and capacities.

6. (Smallpox) Appoint a liaison from the state or local LRN-member laboratory to participate in meetings and conference calls with smallpox steering committee, stakeholders, and any other activities relevant to LRN operations and smallpox activities.

Strategies: What overarching approach(es) will be used to undertake this activity?

The SLI will appoint staff from the virology laboratory to participate in each of the smallpox committee and workgroup meetings held by state and federal agencies. These staff will communicate relevant information to SLI staff at weekly laboratory BT staff meetings.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

- The SLI will continue to actively participate in the Statewide Smallpox Workgroup of the Statewide Bioterrorism Preparedness and Response Program Advisory Committee. This workgroup meets on a monthly basis and is made up of participants from MDPH, local health departments, local and state first responders, hospital clinicians and emergency management.
- The SLI will appoint a laboratory liaison to attend routine Smallpox Logistics meetings facilitated and attended by

MDPH CD Bureau staff.

- The SLI will appoint a laboratory liaison to participate in weekly smallpox conference calls with the Council of State and Territorial Epidemiologists and CDC.
- These appointed liaisons will convey general activities and laboratory specific information to the SLI Laboratory Director, the Laboratory Preparedness Program Coordinator and SLI BT staff at weekly BT staff meetings.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/ Completion Date*	*Responsible Party*
Participate in monthly Statewide Smallpox Workgroup	On going	Ralph Timperi (SLI Laboratory Director) Barbara Werner (SLI Deputy Director)
Participate in weekly Smallpox Logistics meeting	09/03- On going	David Lynch (Molecular Virology Supervisor)
Participate in weekly smallpox conference calls	09/03- On going	Barbara Werner

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

Progress will be determined if meetings are attended by key staff and reports made at weekly BT staff meetings.

CRITICAL CAPACITY #9: As a member of the Laboratory Response Network (LRN), to ensure adequate and secure laboratory facilities, reagents, and equipment to rapidly detect and correctly identify biological agents likely to be used in a bioterrorist incident.

RECIPIENT ACTIVITIES:

1. Continue to develop or enhance operational plans and protocols that include: (a) specimen/samples transport and handling; (b) worker safety; (c) appropriate Biosafety Level (BSL) working conditions for each threat agent; (d) staffing and training of personnel; (e) quality control and assurance; (f) adherence to laboratory methods and protocols; (g) proficiency testing to include routine practicing of LRN validated assays as well as participation in the LRN's proficiency testing program electronically through the LRN website; (h) threat assessment in collaboration with local law enforcement and FBI to include screening for radiological, explosive and chemical risk of specimens; (i) intake and testing prioritization; (j) secure storage of critical agents; and (k) appropriate levels of supplies and equipment needed to respond to bioterrorism events with a strong emphasis on surge capacities needed to effectively respond to a bioterrorism incident. **(LINK WITH FOCUS AREA D)**

Strategies: What overarching approach(es) will be used to undertake this activity?

To ensure that the SLI laboratory operates as a secure LRN member facility with adequate reagents and equipment to rapidly detect and correctly identify biologic agents, weekly operational meetings chaired by the Laboratory Director are attended by all staff with bioterrorism-related responsibilities to discuss, plan, and review new and existing laboratory activities and information.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

Specimen/samples transport and handling:

- Twenty-three SLI staff from all laboratory sections have been trained and certified to properly package and ship bioterrorism-related specimens. On going training is offered to additional staff on a monthly basis.
- SLI has identified a specimen transportation service for environmental specimens and will establish a formal contract. In the event of a public health emergency, DPH food inspectors will assist in transporting specimens to SLI.
- The pilot courier service for clinical specimens will be expanded to include all diagnostic specimens.

Develop or enhance operational plans and protocols that include worker safety:

- BT personnel have taken a refresher course on the use of full-face respirators and additional training will be provided to existing and new staff as needed.
- SLI will continue to train new BT staff on the use of Powered Air Purifying Respirators (PAPR).
- Sixty-one SLI staff have received Biosafety Cabinet training (Eagleson Institute).
- SLI has purchased an area radiation monitor for screening incoming specimens and is in the process of developing protocols and training in conjunction with the MDPH Radiation Control Program (RCP).
- The MDPH RCP trained 12 BT personnel on the use of Ludlum radiation survey meters, and protocols are in development for use in screening specimens in the lab.
- SLI has purchased a Saber 2000 Ion Mobility Detection device, which will be used to screen specimens for explosive and chemical hazards. Evaluation and protocol development are underway.
- Emergency release buttons have been installed in each of the proximity card restricted laboratories as well as the inner rooms of labs with interlocking doors.

Develop or enhance protocols that include appropriate biosafety working conditions for each threat agent.

- All known or suspect select agents are handled under BSL-3 laboratory conditions, and stored with locking devices on refrigerators, freezers and incubators containing these agents.
- Controlled access systems have been installed in all laboratories handling select agents.
- Agent-specific safety, decontamination, and prophylactic protocols are being revised and updated as necessary.

Develop or enhance protocols for the staffing and training of personnel.

- We currently have five BT personnel trained in conventional microbiological and virologic procedures, four trained in TRF procedures and eight trained in PCR. Training protocols are in place for these procedures and are being revised and updated as needed.
- Additional training in collaboration with law enforcement and first responders is planned to review triage procedures for prioritizing intake and testing of samples prior to analysis.
- Staff will attend appropriate conferences, workshops and trainings related to testing.

Develop or enhance protocols that include quality control and assurance.

- All BT reagents and media are subjected to quality control and assurance required in any CLIA certified laboratory. Monthly quality control meetings are attended where media/reagent logs, BT test logs, temperature charts, problem logs, pipette calibration records and employee competency records are reviewed. Deficiencies are noted and corrective actions appropriately documented.
- SLI will enhance the use of simulated and non-select agent materials for in-house proficiency testing samples.

Develop or enhance protocols that include adherence to laboratory methods and protocols.

- Personnel are trained to follow LRN protocols. LRN Standard Operating Procedures are located in the laboratory. In addition, summarized LRN protocols have been written and laminated for easy use at the bench.
- Primary BT personnel are trained on all LRN validated assays and given a proficiency test to demonstrate competency twice a year. The proficiency test is comprised of a written quiz and several unknown samples, which must be ruled out or confirmed as containing BT agents.
- SLI currently participates in all LRN proficiency testing and all BT-related CAP surveys.

Threat assessment in collaboration with local law enforcement and FBI to include screening for radiological, explosive and chemical risk of specimens

- Current HazMat protocols ensure screening for radiation, explosives and chemical risks prior to submission to SLI.
- SLI has purchased Ludlum radiation survey meters, an area radiation monitor and a Sabre 2000 ion mobility detector. Protocols are being developed to utilize these instruments in our specimen receiving area to screen incoming environmental specimens not previously screened.
- A glovebox/filtration unit will be purchased to provide a self-contained system for the safe handling and threat assessment of specimens in the specimen receiving area.

Intake and testing prioritization

- Operational plans prioritize testing for environmental specimens according to presence of a verbal or written threat, likelyhood of target, presence of visible powder and number of exposed victims.
- A 24/7 rotating on call system allows for testing of priority specimens as needed.

Secure storage of critical agents

- All critical agents are stored in laboratories with controlled access as outlined in Critical Capacity 9, Recipient Activity 6.
- Within individual restricted laboratories, freezers, refrigerators, cabinets and other containers where critical agents are stored remain locked at all times with limited access by key or combination. Procedures are in place for replacing compromised keys and combinations.
- An SOP outlines protocols for daily use of select agents and toxins, which is recorded, and monthly inventories of all containers of select agents and toxins are conducted with provisions for reporting loss, theft and accidental release of agents.
- Separate evidence incubators are now in use in the BSL-3 laboratory for specimen growth.

Appropriate levels of supplies and equipment needed to respond to bioterrorism events with a strong emphasis on surge capacities needed to effectively respond to a bioterrorism incident

- Supplies are on hand to handle a surge of 500 specimens and contracts are in place to order additional supplies if needed. Up-to-date inventories are kept of supplies and reagents.
- Equipment is in place for running assays on a variety of platforms. One ABI 7000 and an iCycler will be ordered for real time PCR to increase capacity for testing specimens.
- An additional six-foot biosafety cabinet with duct work will be purchased for the Tuberculosis lab for sample processing and handling.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/ Completion*	*Responsible Party*
State-wide Specimen Courier Service	12/03-	Phyllis Madigan (Director of Client Services)

Develop protocols and training for radiation detection equipment	On going-08/03	Stephen Ridley (Central Lab Services Supervisor) Mariah Grazioplene Thomas O'Connell (Radiation Control Program)
Saber 2000 Protocol Development and Training	On going-08/03	Julie Nassif (Environmental Chemistry Lab Director) Paul Servizio (Chemist)
Revise safety, decontamination and prophylactic agent-specific protocols	On going	Sandra Smole (BioThreat Advanced Technology Lab Director) Cheryl Gauthier (BAT Lab Supervisor) David Lynch (Molecular Virology Supervisor) Raimond Konomi (Virology Supervisor) Bob Goldbaum (Food Testing Laboratory Supervisor)
Train existing and new staff on agent specific protocols	10/03- On going	Sandra Smole; Cheryl Gauthier; David Lynch; Raimond Konomi; Bob Goldbaum
Hire a Food Microbiologist	09/03-11/03	John Fontana (PFGE and Surveillance Director); Bob Goldbaum
Enhance use of simulated and non-select agent materials for in-house proficiency testing	11/03- On going	Sandra Smole; Cheryl Gauthier
Train BT staff on specimen triage protocols	10/03- On going	Mariah Grazioplene

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

The existing weekly BT meetings, chaired by the SLI Lab Director, are used to plan laboratory and emergency activities, evaluate progress, and to share information and problems. Microsoft Project will be used to track progress for review at these meetings to ensure completion of tasks.

2. **CRITICAL BENCHMARK #13:** Ensure capacity exists for LRN validated testing for all Category A agents and other Level B/ C protocols as they are approved.

Strategies: What overarching approach(es) will be used to undertake this activity?

To ensure that capacity exists for LRN validated testing for all Category A agents and other Level B/C protocols, weekly operational meetings are coordinated by the Laboratory Preparedness Coordinator and chaired by the SLI Laboratory Director. These meetings are attended by all BT-related staff to discuss, plan, and review new and existing

laboratory protocols and validations.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

- Technical personnel are trained on multiple agents and BT platforms. Currently we have five BT personnel trained in conventional microbiological and/or virologic procedures, four trained in TRF procedures and eight trained in RT- PCR.
- Available molecular platforms include ABI 5700, SmartCycler, iCycler and Light Cycler. Staff will be trained to use all platforms in the event of a surge situation.
- For surge capacity, staff from other departments have been cross-trained to process specimens and perform data entry and management.
- Existing and new laboratory personnel are offered vaccinations for both anthrax and smallpox. Informational programs are being provided routinely on these vaccines by the MDPH CD Bureau.
- SLI staff will attend CDC and NLTN sponsored training courses.
- The interim FDA protocols for food testing of the four agents (*B. anthracis*, *Brucella* spp., *F. tularensis*, and *Y. pestis*) are being reviewed by our in-house food testing laboratory. Once hired, the Food Microbiologist will become proficient in performing the FDA interim protocols and will train additional staff for surge capacity.
- As part of the pustular rash illness algorithm, conventional and molecular testing for HSV and conventional cell culture for enteroviruses has been implemented. Enteroviral real time PCR capability is under development.
- SLI will continue to validate and train staff on newly released LRN protocols.
- The table below represents our current reagent availability and test capability for the Category A agents listed:

Massachusetts State Laboratory Institute

LRN REAGENT & TEST CAPACITY

AGENTS	Conventional							PCR			TRF	MAT
	Misc.	Slide	Phage	DFA	Shell Vial	Monovalent Antitoxin (A, B, E, F)	Trivalent Antitoxin (A, B, E)	Smart Cycler	Light Cycler	ABI 5700/7000	TRF	MAT
B. anthracis	x		x	x				x	x	x	x	
Brucella spp.	x	x						x	x	x		
Burkholderia spp.								x	x	x		
C. botulinum						x	x					
C. burnetti												
F. tularensis	x	x		x				x	x	x	x	x
Y. pestis	x		x	x				x	x	x	x	
Ricin Toxin											x	
S. enterotoxin B											x	
Orthopox												
Vaccinia				x	x			x	x	x		
VZV				x	x			x	x	x		
Variola								x	x	x		

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/ Completion Date*	*Responsible Party*
Validate and train staff on new protocols	On going	Sandra Smole (BAT Lab Director) Cheryl Gauthier (BAT Lab Supervisor) Zenda Berrada (Molecular Microbiologist) David Lynch (Molecular Virology Supervisor) Raimond Konomi (Virology Supervisor)
Review and implement Interim FDA LRN Food Testing Protocols	12/03 – 03/04	TBD (Food Microbiologist)

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

The existing weekly bioterrorism meetings, chaired by the SLI Laboratory Director, are used to plan laboratory and emergency activities, evaluate progress, and to share information and problems. The timelines generated as part of this grant will be reviewed at these meetings to ensure completion of tasks.

3. Ensure at least one public health laboratory in your jurisdiction has the appropriate instrumentation and appropriately trained staff to perform CDC-developed real-time polymerase chain reaction (PCR) and time-resolved fluorescence (TRF) rapid assays. Integrate new advanced rapid identification methods approved by the LRN into the current laboratory-testing algorithm for human, environmental, animal or food specimens. Contact CDC technical support staff for further information on approved equipment as necessary. **(LINK WITH FOCUS AREA B)**

Strategies: What overarching approach(es) will be used to undertake this activity?

The SLI has trained multiple personnel in both PCR and TRF methodologies for the detection of biological agents. We currently have five BT personnel trained in conventional microbiological and/or virologic procedures, four trained in TRF procedures and eight trained in PCR procedures. Those individuals have been trained on multiple PCR platforms (Smart Cycler, Light Cycler, ABI 5700 and iCycler) to ensure diversity for surge capacity. The SLI will continue to develop and implement molecular epidemiologic methods such as spoligotyping, MLVA, MLST, RFLP, PFGE, ribotyping and sequencing. The operational BT meetings coordinated by the Laboratory Preparedness Coordinator and chaired by the SLI Laboratory Director are used to discuss needs for laboratory instrumentation and additional staff.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

- SLI will purchase an ABI 7000 and an iCycler to replace the existing ABI 5700 and ensure greater capacity of instrumentation.

- The SLI will purchase a digital camera for attachment to a microscope for DFA and cell culture procedures.
- The SLI is currently applying multiple locus variable tandem repeat analysis (MLVA) and multilocus sequence typing (MLST) to different food-borne pathogens.
- The SLI will train additional staff to perform these molecular epidemiologic methods.
- The SLI will identify target genes for confirmatory PCR/sequencing for each Category A agent.
- The SLI will continue to use Pulsed Field Gel Electrophoresis (PFGE) testing for agents such as *E. coli* O157:H7; shiga toxin-producing, non-O157:H7 *E. coli*; *Salmonella* serotypes; *Shigella sonnei*; and *Listeria monocytogenes*.
- The SLI will continue to conduct surveillance susceptibility testing to determine antimicrobial resistance trends and identification of unusual antimicrobial resistance profiles.
- The SLI will use a MicroScan Walkaway, an automated bacterial/susceptibility system, to allow for higher throughput of susceptibility testing.
- The SLI will use an automated ribotyping system, the Riboprinter, for use in rapid identification of a multidrug-resistant strain of *S. Newport*.
- The SLI will continue use of the Riboprinter for rapid species identification of bacteria derived from spores found in biological threat letters after *Bacillus anthracis* has been ruled out by conventional microbiological methods.
- The SLI is evaluating the use of the Riboprinter with custom antibiotic resistance gene probes to characterize chromosomal and plasmid DNA in *S. Newport* MDR-Amp C.
- The SLI is currently evaluating the BAX System for real-time PCR detection of *E. coli* O157:H7 and *Salmonella* spp. in stool.
- The SLI will continue on going development, implementation and training of spoligotyping, RFLP and DNA sequencing to evaluate transmission of multi-drug resistant TB.
- The SLI will continue to train additional and new staff in both PCR and TRF technologies.
- SLI will continue to participate in CDC sponsored validations, carry out proficiency/competency assessments and train personnel on new protocols as they are released.
- To provide automated capacity for sample processing, we will purchase a Roche MagNA Pure LC System to provide automated nucleic acid isolation and purification for LRN real-time PCR applications.
- BT identification protocols released by the LRN for the Biolog Automated System for the Rapid Identification of Bacteria will be implemented.
- SLI requests funding for maintenance contracts on all RTD-PCR platforms, TRF instruments, DNA sequencers and the Biolog Automated System.
- SLI staff will attend appropriate CDC/NLTN sponsored training courses for relevant technologies.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/*	*Responsible Party*
Train staff on molecular methods	On going-12/03	Sandra Smole (BAT Lab Director)
Develop custom Riboprinter probes to further	On going-01/04	John Fontana
Validate use of BAX System for *E. coli* and	01/04-06/04	John Fontana
Validate operation of MicroScan Walkaway	06/04-09/04	John Fontana
Implement Biolog protocols for BT testing	09/03-05/04	Peter Belanger (LRN Coordinator)

Implement Biolog protocols for BT testing	09/03-05/04	Peter Belanger (LRN Coordinator)

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

Competency of newly trained staff will be measured by regular proficiency assessment. Monthly SLI/CD Bureau summaries using the methodologies described above in monitoring outbreaks and surveillance will include comparisons with conventional methodologies.

4. **CRITICAL BENCHMARK #14:** Conduct at least one simulation exercise per year, involving at least one threat agent in Category A, that specifically tests laboratory readiness and capability to perform from specimen threat assessment, intake prioritization, testing, confirmation, and results reporting using the LRN website. **(MAY LINK WITH ALL FOCUS AREAS)**

Strategies: What overarching approach(es) will be used to undertake this activity?

In conjunction with state and local first responders, emergency management, federal partners and area hospitals, MDPH will conduct at least one BT simulation exercise involving at least one Category A threat agent during funding year four.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

- MDPH will contract out the exercised drill program as outlined in Focus Area A, Critical Capacity 3, Recipient Activity 4.
- SLI will specifically contract with a vendor to conduct a scenario-driven panel discussion/tabletop exercise involving one of the Category A agents. The target audience will include sentinel laboratory microbiologists, medical paractitioners and public health professionals.
- SLI will ensure that the simulation exercises will evaluate each of the following components of the response effort:
  - Emergency response
  - Field screening
  - Sample collection
  - Packaging and shipping
  - Sample intake at SLI
  - Laboratory analyses
  - Patient management
  - Data reporting
  - Risk management and risk communication

Timeline: What are the critical milestones and completion dates for each task?

See Focus Area A, Critical Capacity 3, Recipient Activity 4.

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Focus Area A, Critical Capacity 3, Recipient Activity 4.

Ralph Timperi and Mariah Grazioplene will ensure that the exercise evaluates the components listed above.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

Progress will be determined by meeting with SLI BT staff and appropriate outside agencies to review evaluation reports for each component.

5. Ensure the availability of at least one operational Biosafety Level 3 (BSL-3) facility in your jurisdiction. If not immediately possible, BSL-3 practices, as outlined in the CDC-NIH publication "Biosafety in Microbiological and Biomedical Laboratories, 4th Edition" (BMBL), should be used (see www.cdc.gov/od/ohs) or formal arrangements (i.e., MOU) should be established with a neighboring jurisdiction to provide this capacity.

Strategies: What overarching approach(es) will be used to undertake this activity?

To ensure an operationally safe and certified BSL-3 facility at SLI, weekly meetings are coordinated by the Laboratory Preparedness Coordinator and are attended by all BT-related staff to review new and existing laboratory issues. An additional renovation committee has met with an architectural firm to provide information for plans to renovate and upgrade existing and new BSL-3 space in the facility.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

- SLI will upgrade the air handling system to assure consistent negative pressure and temperature in our currently operational BSL-3 laboratory.
- SLI will replace the existing BSL-3 laboratory autoclave.
- To enhance the existing BSL-3 space for smallpox testing, a shower will be installed in the gowning area.
- To provide additional surge capacity BSL-3 laboratory space, SLI has hired an architectural/engineering firm to design renovations to upgrade and enhance its tuberculosis and virology laboratories to BSL-3 for surge testing and to increase capabilities for testing additional agents and matricies.
- Currently, the existing BSL-3 space is outfitted with a CO_2 incubator, an inverted microscope, and electron microscopy supplies to handle highly suspect virology specimens in an emergency situation.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/ Completion Date*	*Responsible Party*
Renovate and upgrade existing TB laboratory	06/03- 08/04	Ralph Timperi (SLI Lab Director); Renovation Committee
Design and plan for personnel shower in BSL-3	09/03	Sandra Smole (BAT Lab Director)
Design and plan to upgrade air handling system in BSL-3	10/03	SLI Lab Director; Renovation Committee
Replace autoclave in BSL-3 laboratory	11/03	Sandra Smole
Renovate and upgrade existing virology lab	08/04-08/05	Ralph Timperi; Renovation Committee

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

The existing weekly bioterrorism meetings, chaired by the SLI Laboratory Director, and the renovation committee meetings are used to evaluate progress and facility plans. The timelines generated as part of this grant will be reviewed at these meetings to ensure completion of tasks.

6. Ensure that laboratory registration, operations, safety, and security are consistent, at a minimum with the requirements set forth in Select Agent Regulation (42 CFR 73) "Possession, Use and Transfer of Select Agents and Toxins; Interim Final Rule" and any subsequent updates as detailed in www.cdc.gov/od/sap and www.aphis.usda.gov/vs/ncie/bta.html. Pursuant to 18 USC section 175b, as added by section 817 of the USA PATRIOT Act of 2001, P.L. 107-56, aliens (other than aliens lawfully admitted to the United States for permanent residence) are prohibited from possessing select agents if they are nationals of countries as to which the Secretary of State (pursuant to provisions of the Export Administration Act of 1979, the Foreign Assistance Act of 1981, or the Arms Export Control Act) has made an unrevoked determination that such countries have repeatedly provided support for acts of international terrorism. **(LINK WITH FOCUS AREA D)**

Strategies: What overarching approach(es) will be used to undertake this activity?

The SLI has designated a Responsible Official (RO) and three Alternate Responsible Officials (AROs) that meet on a biweekly basis to ensure laboratories are consistent with the minimum requirements set forth in the federal Select Agent Regulations through completion, regular review and compliance with in-house protocols for registration, safety, security, emergency response, training and records.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

Registration:

- The SLI has applied for a certificate of registration and has received a temporary registration number.
- The Laboratory Director, Principle Investigator or Select Agent Laboratory Supervisor will submit the names of any new employees for select agent access to the RO who will amend the registration and begin the paperwork for DOJ/FBI security clearance including relevant country of origin determinations.
- When additional select agents need to be registered, the Principle Investigators must notify the RO who will amend the registration.

Safety:

- SLI has developed an interim safety plan, which is currently being enhanced to include detailed aspects of select agent use and storage. Plans include biosafety standards for BSL-2 and BSL-3 operation and requirements for handling toxins as well as customized biosafety guides for responding to exposures of each select agent and toxin.
- SLI will renovate the specimen receiving area to improve the safety of accepting environmental specimens perceived to be a threat.
- SLI will purchase a glove box for processing environmental specimens in the specimen receiving area.
- SLI has purchased a Ludlum radiation survey meter, an area radiation monitor, and a Sabre 2000 Ion Mobility detector for screening environmental specimens for radiation, explosives and chemicals. Protocols and training

are in development for these instruments.

Security:

- A risk assessment and threat analysis of SLI is on going with members of the Massachusetts State Police Task Force, facility senior management staff, engineering officials and health and safety officials. The goal is to define threats against the vulnerabilities of the laboratory in order to determine the necessary components required for a complete facility security plan specific to the SLI.
- Physical security of the individual laboratories within SLI are also being assessed to prevent unlawful access to restricted laboratory areas where select agents are stored, to enhance employee security and to address breaches in security.
- Employee identification cards must be worn at all times when inside the building. Employees gain access to the building by swiping their identification card through a card reader, which is electronically recorded.
- The building security camera system will be enhanced with the placement of digital cameras at all building entrances as well as hallways and doorways of restricted areas. These digital files will be saved and stored in a secure location.
- Employees authorized for access to a restricted select agent area use a dual authentication system including fingerprint readers and identification card proximity scanners for entrance and exit of the area. The system is monitored electronically and reports are generated weekly to check for any violations. This system will be enhanced by the addition of proximity readers at hallway and stairwell access points.
- Protocols are in place to electronically record all escorted and monitored visitors who access restricted areas.
- All freezers, refrigerators and incubators where select agents are stored are secured with combination and/or key locks. The select agent laboratory supervisor is responsible for maintaining security for agents in restricted access areas.

Emergency Response

- The present facility emergency response and contingency plan is under review to ensure protocols specific to select agents are being integrated into the plan such as hazards associated with select agents and toxins, evacuation, decontamination, response actions associated with outside parties, communication, and prevention.
- These protocols include specific activities associated with loss, theft and release of select agents, bomb threats, severe weather situations, power outages and other natural disasters.

Training Programs

- A total of 61 SLI employees (including all employees registered in the select agent program) attended an all day Biological Safety Cabinet training course offered by the Eagleson Institute of Sanford, ME and received certification. A similar program is being prepared to educate employees about the proper usage of chemical fume hoods.
- All SLI employees registered in our Select Agent Application have attended training on use of the Laboratory Security System.
- All SLI employees registered in our Select Agent Application are in the process of attending a comprehensive eight-hour mandatory training program on packaging and shipping laboratory specimens including select agents utilizing IATA, DOT, CDC, USPS and specific carrier regulations.
- Yearly training will be mandatory for all registered SLI Select Agent employees on security, safety, emergency response, and record keeping protocols. The RO and AROs are in the process of developing the curricula for these training programs.

Records

- Any person not authorized for access to a restricted select agent area including full-time and part-time employees, maintenance workers, janitors, and contractors must fill out the visitor security agreement and sign the visitor access log.
- To address select agent accountability, an inventory system was set up in the fall of 2002. Procedures have been put into place for maintaining a monthly inventory of select agents and toxins used at the SLI as well as

procedures accounting for daily use and access to storage locations (SOP-"Select Agent Inventory Management").

- All employees registered to work in select agent areas must fill out the "Record of Laboratory Security System Employee Access" form, which tracks level of access and access termination.
- Each laboratory supervisor and employee with access to select agent storage units must fill out the "Record of Access to Select Agent Storage Units" form. The RO maintains up-to-date records of authorization for entry into restricted areas and those who possess keys and combinations.
- Procedures have been developed for transferring and shipping select agents to and from the SLI and include: an SOP entitled "Procedure for Packaging and Shipping Diagnostic Samples and Infectious Substances"; an SOP entitled "Procedure for Registration, Amendment to Registration, Transfer, Theft Loss, Release and Destruction of Select Agents and Toxins". These SOPs address appropriate record keeping and RO notification protocols.
- All records pertaining to select agents are retained by the RO for at least three years.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/ Completion Date*	*Responsible Party*
Develop curricula for select agent training	On going – 12/03	Phyllis Madigan (Director of Client Services, RO) Mariah Grazioplene (Lab Preparedness Coordinator, ARO) Peter Belanger (LRN Coordinator, ARO) Kristin Laird (Training Advisor, ARO)
Update facility safety plan	On going-09/03	Phyllis Madigan; Mariah Grazioplene; Peter Belanger; Kristin Laird
Renovate Specimen Receiving	08/03-12/03	Ralph Timperi; Renovation Committee
Develop protocols and training for radiation detection equipment	On going-08/03	Stephen Ridley (Central Lab Services Supervisor) Mariah Grazioplene Thomas O'Connell (Radiation Control Program)
Saber 2000 Protocol Development and Training	On going-08/03	Julie Nassif (Environmental Chemistry Lab Director) Paul Servizio (Chemist)
Complete SLI risk assessment	On going-12/03	MA State Police; Phyllis Madigan; Mariah Grazioplene; Peter Belanger; Kristin Laird
Update facility emergency response and contingency plan	On going-09/03	Phyllis Madigan; Mariah Grazioplene; Peter Belanger; Kristin Laird

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

SLI will determine progress by RO assessment of compliance with Select Agent Regulations through monthly select agent meetings with select agent lab supervisors and principle investigators; periodic inspections of select agent labs

and storage areas; and by reviewing evaluation by select agent site visitors.

7. Enhance electronic communications and LRN electronic laboratory reporting, at the bench level, to enable integration with CDC's LRN capacity monitoring efforts, online results reporting, sentinel surveillance, proficiency testing, multi-center validation studies, and support for future LRN site enhancements. Laboratories should participate in reporting results of LRN proficiency testing electronically, as they would in an actual event. Laboratories should have appropriate computer equipment, firewall and high-speed Internet connectivity to access the LRN's protocols, reagents, and lab user applications. **(LINK WITH FOCUS AREA D, E AND CROSS CUTTING ACTIVITY *LABORATORY DATA STANDARD*, Attachment X)**

Strategies: What overarching approach(es) will be used to undertake this activity?

The SLI will continue to enhance its electronic communications capabilities to provide secure, timely test reporting and surveillance information to the LRN, other private entities and government agencies to support public health disease reporting and surveillance activities. SLI has recently completed the conceptual design of the SLI Electronic Laboratory Reporting and Communication (ELR) Component. The ELR component will allow SLI to provide secure client transactions through web-based communications.

The ELR component is an extranet application that will extend the functionality of the recently developed State Laboratory Information System (SLIS). SLIS includes a common data repository (CDR) that will be accessed by all laboratories within the SLI. The CDR is based on the NEDSS/HL7 logical data model and utilizes common database technology (SQL Server) using Windows NT and supports ODBC connectivity.

The conceptual design of the ELR Component includes the use of a commercial interface engine as a solution for both ELR and SLIS transmission and reception of HL7 messages and data. The interface engine will be selected to support HL7, Version 2.4 and earlier, ebXML, message queues and the ability to translate and manipulate LOINC and SNOMED codes. The web interface will use standard web security features of the web server platform, which will be selected during the detailed design phase, and include strong authentication connectivity. These include HTTP User Authentication and session encryption using HTTPS and secure socket layer (SSL).

Tasks: What key tasks will be conducted in carrying out each identified strategy?

- Define the detailed requirements of the ELR Component of State Laboratory Information Systems (SLIS) to report laboratory results to the LRN, other private entities and government agencies using HL7 messaging and remote laboratory test result inquiry capabilities.
- Determine the readiness of select hospitals and laboratories to report results electronically including an evaluation of their HL7 interface capabilities.
- Ensure that system participants have Internet Connectivity and that the connection is a minimum of 56Kbps (ideally 384 Kbps or greater) and can support 128 bit encryption.
- Create functional specifications that include the defined business logic, data requirements and information processing. This also will include the identification of potential COTS solutions
- Refine technical architecture including specifications of the optimum technology associated with the hardware, software, communications and interface of the ELR Component. The architecture will include integration with the SLIS application within an n-tier architecture.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Start Date/ Completion Date*	*Responsible Party*
Define the detailed requirements of the ELR Component	07/03 – 09/03	Dina Caloggero (QA and Informatics Manager) Siu Leung Cheung (EDP Systems Analyst) John Schaeffer/James Daniel (CD Bureau) TBD (EDP Systems Analyst)
Determine the readiness of select hospitals and laboratories to report results electronically	07/03 – 09/03	Dina Caloggero; Siu Leung Cheung; John Schaeffer; James Daniel; TBD (EDP Systems Analyst)
Ensure that system participants have Internet Connectivity	07/03 – 09/03	Dina Caloggero; Siu Leung Cheung; John Schaeffer; James Daniel; TBD (EDP Systems Analyst)
Create functional specifications	09/03 – 12/03	Dina Caloggero; Siu Leung Cheung; John Schaeffer; James Daniel; TBD (EDP Systems Analyst)
Refine technical architecture	12/03 – 03/04	Dina Caloggero; Siu Leung Cheung; John Schaeffer; James Daniel; TBD (EDP Systems Analyst)

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

The ELR Component will be developed in accordance with the MDPH, Systems Development Life Cycle (SDLC) methodology. Metrics will be employed on selected tasks as appropriate to monitor performance, identify potential issues as early as possible in the SDLC process and determine the effectiveness of remedial actions taken. Major milestone dates will be monitored as to the estimated and actual completion dates. Once the metrics are defined and gathered, they will be communicated regularly to the SLI Project Team for project tracking and process improvements.

8. (Smallpox) Identify the laboratories that have the capacity for LRN-validated testing and reporting of *Variola major, Vaccinia and Varicella* through human and environmental samples. Each state should have at least one laboratory that can meet CDC biosafety and security requirements for variola-specific testing.

Strategies: What overarching approach(es) will be used to undertake this activity?

Approaches used to undertake this activity will be to carry out the testing and reporting at SLI and utilize the Harvard School of Public Health Electron Microscopy Facility for the EM work.

Tasks: What key tasks will be conducted in carrying out each identified strategy?

The SLI has been identified as having the capacity for LRN-validated testing and reporting of *Variola major*, vaccinia and varicella and meeting the CDC biosafety and security requirements for variola-specific testing.

- Implement varicella and vaccinia testing as well as HSV (1/2) and enterovirus testing for pustular, rash illness algorithm.

- Assure adequate number of lab staff have received smallpox vaccine.
- Request funds for facility upgrades necessary to meet BSL-3+ recommendations for smallpox.
- Locate EM facilities in jurisdiction.
- Develop coordinated plans with sentinel labs for specimen collection and processing for low, moderate and high risk patients.
- Implement orthopox and *Variola major* testing when LRN protocols and reagents are available.

Timeline: What are the critical milestones and completion dates for each task?

Task	*Timeline*	*Responsible Person*
1. Varicella/Vaccinia (V/V)		
V/V testing by LRN protocols and conventional shell vial tests	Implementation and validation completed. Ongoing: train additional personnel/March 2004	David Lynch (Molecular Virology Supervisor) Raimond Konomi
V/V CLIA compliance	Complete with exception of vaccinia DFA and shell vial Ongoing/ Aug 2003	David Lynch Raimond Konomi
HSV (1/2), enteroviruses testing By PCR and conventional methodology	Implemented CLIA validations and additional training ongoing/ Sept 2003	David Lynch Raimond Konomi Scott Hennigan
2. Smallpox Vaccination	3 lab staff vaccinated Ongoing: 4 additional staff/ July 2003; subsequent additional staff March 2004	Mariah Grazioplene (Lab Preparedness Coordinator)
3. BSL-3	One unit completed Ongoing: surge area /August 2004 Additional virology area/August 2005	Ralph Timperi (SLI Lab Director) Renovation
4. EM facilities		
Initial site visit/training plan for smallpox evaluation by EM	Completed June 2003 and on going Ongoing: establishment training contract for SLI staff July 2003	David Lynch Harvard SPH
Local sampling handling protocols to complement LRN protocol	Ongoing: Sept. 2003	David Lynch
Additional SLI staff trained for prep of grids and EM evaluation	Dec. 2003	David Lynch
5. Specimen Collection Plan		

Response team in conjunction with smallpox workgroup	Plans in place for lab/medical team Ongoing refinement and additional members to be trained/March 2004	Barbara Werner
VTM validated for V/V transport	Completed	Raimond Konomi

Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.

See Timeline.

Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?

Progress will be assessed through reports at weekly BT meetings at SLI and by reports to and feedback from the statewide Smallpox workgroup. In addition, routine proficiency/competency assessment of staff performing tests will be carried out and timelines will be checked at monthly intervals by responsible individuals.